OCT 2 0 2000

K002581

XI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS. Aug. 15, 2000
[Separate Page]

I.* Submitter: George Wolfe, Sultan Dental Products, Inc., Englewood, N.J., phone: 201-894-5500

II. Classification Names and numbers: Varnish, cavity, Class II, 76LBH

III. Common/Usual Name: Cavity varnish

IV. Proprietary Names: DuraGard[R] Fluoride Varnish

V. Establishment Registration Number: 2248078

VI. Classification: Cavity varnishes were classified by the Dental Devices Panel into Class II. They are described under CFR 872.3260.

VII. Substantial Equivalence: DuraGard[R] Fluoride Varnish is substantially equivalent to the originally classified device described in CFR 872.3260 "Varnish, cavity." It is also substantially equivalent and nearly identical to (for example) the following products that are currently on the market, having been cleared by 510(k)s:

510(k) Number	Name of Device	Company
K-982915	Sci-Pharm DFV Varnish	Scientific Pharmaceuticals, Inc.
K-983305	Sci-Pharm Desensitizing Varnish	" " "
K-945794	Duraphat	Inpharma
K-961893	Duraflor	Pharmascience, Inc.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, as a varnish on sensitive teeth over exposed dentin under temporary restoratives and cements and exposed dentin on roots, as many cleared by the 510(k) process as shown above.

2. The technological characteristics for this product are the same as those for the predicate devices and other resinous products currently on the market except for minor variations in the same or similar components.

3. Descriptive information provided shows that the materials from which Sultan™ Densensitizing Varnish is made are substantially equivalent to (nearly identical with some) those of similar products, used for identical purposes, currently on the market.

4. The FDA "Decision-Making Process" chart was used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2000

Mr. George Wolfe
Marketing Manager
Sultan Dental Products, Limited
242 South Dean Street
Englewood, New Jersey 07631

Re: K002581
Trade Name: DuraGard Sodium Floride Varnish
Regulatory Class: II
Product Code: LBH
Dated: August 15, 2000
Received: Agust 18, 2000

Dear Mr. Wolfe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

this letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VIII.1 Indications for Use: [Separate Page]

510(k) Number: NA K002581

Device Name: DuraGard® 5% Fluoride Varnish

Intended for use as a varnish on sensitive teeth over exposed dentin under temporary restoratives and cements where post-operative sensitivity is a concern and to improve quality and functionality of restorations when used in conjunction with dental restoratives and cements.

To seal dentinal tubules in cavity preparations or on sensitive root surfaces.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use_____ (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off) 3
Division of Dental, Infection Control,
and General Hospital Devices

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